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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/078,927

02/19/2002

Thomas Curran

SJ-01-0032

6357

28258

7590

09/03/2009

ST. JUDE CHILDREN'S RESEARCH HOSPITAL  
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EXAMINER

STEADMAN, DAVID J

ART UNIT

PAPER NUMBER

1656

MAIL DATE

DELIVERY MODE

09/03/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/078,927	<b>Applicant(s)</b> CURRAN ET AL.	
	<b>Examiner</b> David J. Steadman	<b>Art Unit</b> 1656	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 10 September 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 4-8, 10, 11, 13-15 and 36-38 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 4-8, 10, 11, 13-15 and 36-38 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)<br>2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)<br>3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____. | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date _____.<br>5) <input type="checkbox"/> Notice of Informal Patent Application<br>6) <input type="checkbox"/> Other: _____. |
|---|---|

## **DETAILED ACTION**

### ***Status of the Application***

- [1]** Claims 4-8, 10-11, 13-15, and 36-38 are pending in the application.
- [2]** Applicant's amendment to the claims, filed on 9/10/08, is acknowledged. This listing of the claims replaces all prior versions and listings of the claims.
- [3]** Receipt of a substitute sequence listing, filed on 12/17/08, is acknowledged.
- [4]** Applicant's remarks filed on 9/10/08 in response to the non-final Office action mailed on 6/19/08 are acknowledged. Applicant's arguments have been fully considered.
- [5]** The text of those sections of Title 35 U.S. Code not included in the instant action can be found in a prior Office action.

### ***Specification/Informalities***

- [6]** The objection to the specification as introducing new matter by way of the specification amendments filed on 4/25/2005 and 11/21/2005 is withdrawn in view of the sequence listing filed on 12/17/08, which removes SEQ ID NO:4 and 5. SEQ ID NO:1-3 as set forth in the 12/17/08 sequence listing appear to be identical to the original sequence listing as filed on 2/19/02.

### ***Claim Rejections - 35 USC § 103***

- [7]** The rejection of claims 4-8 and 36-37 under 35 U.S.C. 103(a) as being unpatentable over Curran in view of Keshvara, Niethammer, Carr, and GenBank

Accession Numbers 1771281 and 3288851 is maintained for the reasons of record and the reasons set forth below. In the interest of brevity, it is noted that the rejection was fully explained in a prior Office action. See item [9] beginning at p. 4 of the Office action mailed on 6/19/08.

RESPONSE TO ARGUMENT: Beginning at p. 4 of the remarks filed on 9/10/08, applicant argues the invention is based on the discovery that Dab1 is selectively phosphorylated by Cdk5 on Ser491 and Ser515. Applicant argues this discovery is important and non-obvious because it provides a method for detecting Cdk5 activity in a biological sample, which method is different from a method for determining the sites of Dab1 phosphorylation by Cdk5. According to applicant, there was no way to predict *a priori* that certain sites in Dab1 would be phosphorylated only by Cdk5 and provide a method for detecting Cdk5 activity, which, according to applicant, was difficult before the present invention because of the lack of a substrate that is selectively phosphorylated by Cdk5.

Applicant's argument is not found persuasive. The examiner maintains the position that the claimed invention would have been obvious to one of ordinary skill in the art at the time of the invention. While the prior art clearly teaches or suggests Dab1 phosphorylation by Cdk5, the examiner acknowledges that the combination of references does not appear to explicitly teach or suggest phosphorylation of Dab1 by Cdk5 *at residues Ser491 and Ser515*. However, the examiner maintains the position that by practicing the method as taught or suggested by the combination of prior art (as

noted previously at pp. 7-8 of the Office action mailed on 6/19/08), one would have practiced a method that is encompassed by the claims.

Although applicant takes the position that a method for detecting Cdk5 serine kinase activity in a biological sample is different from the method as taught or suggested by the prior art, applicant fails to point out with particularity the difference(s) between the claimed method and the method as taught or suggested by the prior art. Put another way, there is no objective evidence or line of reasoning to support the position that the method as taught or suggested by the prior art is not encompassed by the method as claimed. While the examiner acknowledges the preamble's recitation of "method for detecting cyclin dependent kinase 5...serine kinase activity in a biological sample", this recitation has been interpreted as an intended use of the claimed method and has been accorded no patentable weight with respect to the active method steps of the claims. See MPEP 2106.II.C, which states, "Language that suggests or makes optional but does not require steps to be performed or does not limit a claim to a particular structure does not limit the scope of a claim or claim limitation".

At least for the reasons stated above, the examiner maintains the position that the combination of cited references properly establishes a *prima facie* case of obviousness.

**[8]** The rejection of claim(s) 10-11, 13-15, and 38 under 35 U.S.C. 103(a) as being unpatentable over Curran in view of Keshvara, Niethammer, Carr, and GenBank Accession Numbers 1771281 and 3288851 as applied to claims 4-8 and 36-37 above

and further in view of Howell, Fu, Michalewski, and Zhen is maintained for the reasons of record and the reasons set forth below. In the interest of brevity, it is noted that the rejection was fully explained in a prior Office action. See item [10] beginning at p. 13 of the Office action mailed on 6/19/08.

RESPONSE TO ARGUMENT: Beginning at p. 6 of the remarks filed on 9/10/08, applicant argues it was not obvious that Cdk5 serine kinase activity could be determined by determining the Dab1 serines that are phosphorylated by Cdk5 and that none of the cited references suggests Ser491 and Ser515 of Dab1 as being phosphorylated only by Cdk5. Thus, according to applicant, because there is nothing in the prior art references of Curran, Keshvara, Niethammer and the recited GenBank Accession Numbers to suggest the inventions in claims 6-8 and 36-37, combining Howell, Fu, Michalewski and Zhen with Curran, Keshvara, Niethammer and the recited GenBank numbers does not render obvious the recited antibodies of claims 10-11, 13-14 and 38.

Applicant's argument is not found persuasive. The examiner maintains the position that the claimed invention would have been obvious to one of ordinary skill in the art at the time of the invention. As noted above, the examiner acknowledges that the combination of references does not appear to explicitly teach or suggest phosphorylation of Dab1 by Cdk5 *at residues Ser491 and Ser515*. However, the examiner maintains the position that by practicing the method as taught or suggested by the combination of references (as noted previously at pp. 14-15 of the Office action mailed on 6/19/08), one would have practiced a method that is encompassed by the claims.

Although applicant takes the position that measuring Cdk5 activity is not obvious from the method as taught or suggested by the prior art, applicant fails to point out with particularity the difference(s) between the claimed method and the method as taught or suggested by the prior art. In other words, there is no objective evidence or line of reasoning to support the position that the method as taught or suggested by the prior art is not encompassed by the method as claimed. While the examiner acknowledges the preamble's recitation of "method for detecting cyclin dependent kinase 5...serine kinase activity in a biological sample", this recitation has been interpreted as an intended use of the claimed method and has been accorded no patentable weight with respect to the active method steps of the claims. See MPEP 2106.II.C, which states, "Language that suggests or makes optional but does not require steps to be performed or does not limit a claim to a particular structure does not limit the scope of a claim or claim limitation".

At least for the reasons stated above, the examiner maintains the position that the combination of cited references properly establishes a *prima facie* case of obviousness.

### ***Conclusion***

**[9]** Status of the claims:

Claims 4-8, 10-11, 13-15, and 36-38 are pending.

Claims 4-8, 10-11, 13-15, and 36-38 are rejected.

No claim is in condition for allowance.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Art Unit: 1656

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Steadman whose telephone number is 571-272-0942. The examiner can normally be reached on Mon to Fri, 7:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/David J. Steadman/  
Primary Examiner, Art Unit 1656